



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,105	03/31/2004	James B. Hunt	8627- 431 (PA-5498-RFB)	6585
757 7590 02/19/2009 BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610				
EXAMINER				
RYCKMAN, MELISSA K				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
02/19/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/815,105
Filing Date: March 31, 2004
Appellant(s): HUNT, JAMES B.

Richard E. Stanley, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/5/08 appealing from the Office
action mailed 3/17/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

The status of claims 28-35 was incorrect in the last office action (3/17/08), the Examiner acknowledges that these claims have been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,846,166	Lentz et al.	12-1998
2001/0034550 A1	Burge et al.	10-2001
6,579,314 B1	Lombardi et al.	06-2003
6,387,123 B1	Jacobs et al.	05-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Lentz et al. (U.S. Patent No. 5,843,166).

Regarding Claim 36, Lentz teach a stent graft assembly comprising: a stent structure (28) comprising a luminal surface and an abluminal surface and having at least a first radial opening and a second radial opening, said first and second radial openings extending through said stent structure between said luminal surface and said abluminal surface, wherein said first and second radial

Art Unit: 3773

openings are spaced apart along a first direction; a first graft layer (22') disposed along at least a portion of said luminal surface of said stent structure thereby fully covering a luminal side of said first and second radial openings; a second graft layer (12') disposed along at least a portion of said abluminal surface of said stent structure thereby fully covering an abluminal side of said first and second radial openings; a first attached area securing said first and second graft layers together thought apportion of said first radial opening, wherein a first unattached margin (30a') in which said first and second graft layers are, not secured to each other is disposed between said first attached area and an edge of said first radial opening; a second attached area securing said first graft layer and said second graft layer together through a proton of said second radial opening, wherein a second unattached margin (30b') in which said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and wherein said first and second unattached margins are oriented along said first direction and on a same side of said first and second attached areas, thereby allowing said first and second graft layers to move along said first direction relative to said stent (fig 3, the unattached margin allows small movement in several directions of the stent) and wherein said first unattached margin (30a') extends peripherally all around said first attached area and said second unattached margin (30b') extends peripherally all around said second attached area (it is noted that these are inherent features as defined by the attached and unattached areas).

Art Unit: 3773

Claims 1-11,13,14, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz et al. (U.S. Patent No. 5,843,166), and further in view of Jacobs et al. (U.S. Patent No. 6,387,123).

Regarding Claim 1, Lentz teaches a stent-graft assembly, comprising: at least one unitary stent structure (28) comprising a luminal surface and an abluminal surface and having at least a first radial opening and a second radial opening (between stent portions 28') said first and second radial openings extending through said stent structure between said luminal surface and said abluminal surface; a first graft layer (22') disposed along at least a portion of said luminal surface of said stent structure thereby fully covering luminal sides of said first and second radial openings; a second graft layer (12') disposed along at least a portion of said abluminal surface of said stent structure thereby fully covering abluminal sides of said first and second radial openings (fig. A, in office action, on following page); a first attached area securing said first graft layer and said second graft layer together through a portion of said first radial opening (fig. A), wherein a first unattached margin (see Fig. A on following page, 30a', unattached margin extends completely across opening with the bold line in the drawing) whereby said first and second graft layers are not secured to each other being disposed between said first attached area and an edge of said first radial opening; a second attached area securing said first graft layer and said second graft layer together through a portion of said second radial opening (30b'), wherein a second unattached margin whereby said first and second graft layers are not secured to each other being disposed between said second attached

Art Unit: 3773

area and an edge of said second radial opening; and wherein said first and second unattached margins are oriented along said first direction and on a same side of said first and second attached areas, thereby allowing said first and second graft layers to move along said first direction relative, to said stent (Column 3, proximate lines 42-45).

Lentz does not include struts, however Jacobs teaches said first and second radial openings being axially and circumferentially defined by a plurality of struts (14) thus said first and second radial openings are spaced apart along a first direction.

It would have been obvious to one of ordinary skill in the art to have the struts of Jacobs with the stent and graft of Lentz, because as Jacobs teaches "the struts enable the tube to expand radially when subjected to the appropriate radially directed forces" (col. 4, ll. 13-16).

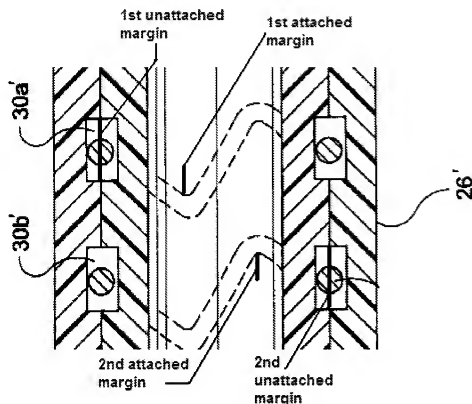


Fig. A: Fig. 3 of Lentz

Regarding Claim 2, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein a size of said first attached area is less than a size of said first unattached margin (30a') and a size of said second attached area is less than a size of said second unattached margin (30b'), see fig. A in office action, the unattached margins extend completely across openings 30b' or 30a'.

Regarding Claim 3, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first direction is axial (see fig. A, small motion of the stent in the axial direction is allowed because the stent is not attached to the graft layers).

Art Unit: 3773

Regarding Claim 4, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first direction is circumferential (fig. A, small motion of the stent in the circumferential direction is allowed because the stent is not attached to the graft layers).

Regarding Claim 5, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first attached area is positioned adjacent another edge of said first radial opening and said second attached area is positioned adjacent another edge of said second radial opening (fig. A), said first and second attached areas thereby being disposed on opposite sides of said struts, whereby said first and second graft layers are restricted from moving along a second direction relative to said stent (graft layers do not move with respect to each other).

Regarding Claim 6, Lentz and Jacobs teach the stent-graft assembly according to claim 5, wherein said first direction is axial and said second direction is circumferential (fig. A, small motion of the stent in the axial direction is allowed because the stent is not attached to the graft layers, the graft layers do not move in a circumferential direction with respect to each other).

Regarding Claim 7, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first unattached margin extends peripherally all around said first unattached margin and said second attached area extends peripherally all around said second attached area (fig. A, unattached margin extends circumferentially around the stent).

Art Unit: 3773

Regarding Claim 8, Lentz and Jacobs teach the stent-graft assembly according to claim 7, wherein a size of said first attached area is less than a size of said first unattached margin (30a') and a size of said second attached area is less than a size of said second unattached margin (30b'), see fig. A.

Regarding Claim 9, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein: a third unattached margin (stent above 30a') whereby said first and second graft layers are not secured to each other is disposed between said first attached area and an edge of said first radial opening; a fourth unattached margin (30c') whereby said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and said third and fourth unattached margins are oriented along a second direction, thereby allowing said first and second graft layers to move along said second direction relative to said stent, said second direction being different than said first direction (graft layers move when stent moves), it is noted that there is sufficient space in the unattached margins for the stent structure to move both longitudinally and circumferentially, see fig. A.

Regarding Claim 10, Lentz and Jacobs teach the stent-graft assembly according to claim 9, wherein a size of said first attached area (24') is less than a size of said third unattached margin and a size of said second attached area is less than a size of said fourth unattached margin (see fig. A).

Regarding Claim 11, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first graft layer (22') covers substantially all of

Art Unit: 3773

said luminal surface of said stent structure and said second graft layer (12') covers substantially all of said abluminal surface of said stent structure.

Regarding Claim 13, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first and second attached areas are attached by thermal bonding (Column 5, proximate lines 40-45).

Regarding Claim 14, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first and second graft layers comprise a synthetic polymer (Column 3, proximate lines 64-67).

Regarding Claim 16, Lentz and Jacobs teach the stent-graft assembly according to claim 1, wherein said first and second attached areas are attached by thermal bonding (Column 5, proximate lines 40-45); and said first and second graft layers comprise a synthetic polymer (Column 3, proximate lines 64-67).

Regarding Claim 17, Lentz and Jacobs teach the stent-graft assembly according to claim 16, wherein: a third unattached margin whereby said first and second graft layers are not secured to each other is disposed between said first attached area and an edge of said first radial opening (30c'); a fourth unattached margin whereby said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and said third and fourth unattached margins are oriented along a second direction, thereby allowing said first and second graft layers to move along said second direction relative to said stent, said second direction being different than said first direction (fig. A), it is noted that there is sufficient space in

Art Unit: 3773

the unattached margins for the stent structure to move both longitudinally and circumferentially, see fig. 3.

Regarding Claim 18, Lentz and Jacobs teach the stent-graft assembly according to claim 17, wherein a size of said first attached area is less than a size of said first unattached margin and a size of said third unattached margin and a size of said second attached area is less than a size of said second unattached margin and a size of said fourth unattached margin (fig. A).

Regarding Claim 19, Lentz and Jacobs teach the stent-graft assembly according to claim 18, wherein said first graft layer (22') covers substantially all of said luminal surface of said stent structure and said second graft layer (12') covers substantially all of said abluminal surface of said stent structure.

Claims 15 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz and Jacobs in view of Buirge et al. (US 2001/0034550).

Lentz and Jacobs teach all limitations of preceding dependent claim 1 and claims 24-34, as previously described with respect to claims 1-11, 13, 14 and 16-19, but fails to teach wherein the graft layers comprise small intestine submucosa attached by thermal bonding. Buirge teaches a stent covered by two grafts, wherein the grafts are formed of submucosa in order to provide a graft material that can hold and release therapeutic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lentz as taught by Buirge in order to provide a graft material that can hold and release therapeutic material.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz and Jacobs in view of Lombardi et al. (US6579314).

Lentz and Jacobs teach all limitations of preceding dependent claim 1, but fails to teach wherein the first and second attached areas are attached using sutures. Lombardi teaches a covered stent having a luminal and abluminal covering sutured together (Column 5, proximate lines 27-30). It would have been an obvious matter of design choice to attach the graft members of Lentz with sutures as taught by Lombardi since applicant has not disclosed that suturing as opposed to welding serves any particular purpose or provides any advantage.

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz and Jacobs, in view of Buirge, and further in view of Lombardi. Lentz and Jacobs teach all limitations of preceding dependent claims 1, 16 and 17, and further all limitations of claims 21-23 as described previously, but fails to teach wherein the graft layers comprise small intestine mucosa and are attached using sutures. Regarding the limitation wherein the graft layers comprise small intestine mucosa, Buirge teaches a stent covered by two grafts, wherein the grafts are formed of submucosa attached by thermal bonding (paragraphs 53-60) in order to provide a graft material that can hold and release therapeutic material.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lentz and Jacobs as taught by Buirge in order to provide a graft material that can hold and release therapeutic material. The combination of Lentz, Jacobs, and Buirge fails to teach wherein the

graft layers are attached using sutures. Lombardi teaches a covered stent having a luminal and abluminal covering sutured together (Column 5, proximate lines 27-30). It would have been an obvious matter of design choice to attach the graft members of Lentz with sutures as taught by Lombardi since applicant has not disclosed that suturing as opposed to welding serves any particular purpose or provides any advantage.

(10) Response to Argument

The Appellant appears to be interpreting the rejection of claim 1 to be substituting the entire structure of Jacobs for the struts of Lentz, although the results would be the same as the Examiner's solution, the Examiner was simply taking the cross struts of Jacobs and adding these to the annular struts of Lentz. Regarding this combination, the unattached margin would be surrounding the struts connecting the annular rings, this unattached margin allows motion because of openings 30a' and 30b', Lentz teaches the struts can move because of these pockets (col. 5, l. 48,49). Regarding the arguments of the unattached and attached margins, the Examiner refers to the description of the unattached and attached margin in claims 1 and 36, these claims state "a first attached area securing said first graft layer and said second graft layer together through *a portion* (emphasis added) of said first radial opening." Regarding the stent moving in an axial or circumferential direction the Examiner notes that a small motion of the stent in the circumferential direction is allowed because the stent is not attached to the graft layers (col. 5, l. 48,49). Regarding the arguments of the

Art Unit: 3773

attached margin extending peripherally all around the first unattached margin, the Examiner is interpreting "all around" to be circumferential, and the first attached margin spreads circumferentially along the top of the first unattached margin. A drawing is included in the above rejection to show the unattached and attached areas as claimed, the unattached margin extends completely across opening the opening, as shown with the bold line.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

MKR

/Melissa Ryckman/

Examiner, Art Unit 3773

Conferees:

Jackie Ho

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773

/Janet C. Baxter/

TC 3700 TQAS